PERFORMANCE OF A NEW REAL-TIME CONTINUOUS GLUCOSE MONITORING SYSTEM: A MULTICENTER PILOT STUDY

Jian Zhou[1–5†], Shuo Zhang[6†], Liang Li[7], Yufei Wang[1–5], Wei Lu[1–5], Chunjun Sheng[7], Yiming Li[6], Yuqian Bao[1–5*], Weiping Jia[1–5].
[1]Department of Endocrinology and Metabolism, Shanghai Jiao Tong University Affiliated Sixth People's Hospital; [2]Shanghai Clinical Center for Diabetes; [3]Shanghai Key Clinical Center for Metabolic Disease; [4]Shanghai Diabetes Institute; [5]Shanghai Key Laboratory of Diabetes Mellitus; [6]Department of Endocrinology and Metabolism, Huashan Hospital Fudan University, and [7]Department of Endocrinology and Metabolism, Shanghai Tenth People's Hospital, Tongji University, School of Medicine, Shanghai, China

INTRODUCTION

Previous clinical studies showed that CGM contributed to the control of blood glucose levels, a reduced occurrence of hypoglycemia, lower levels of hemoglobin A_{1c} (HbA_{1c}), as well as a decreased risk of diabetes complications.

The accuracy of sensor readings is a critical factor for the clinical application of CGM, and the current gold standard assessment method in terms of accuracy is measurement of the glucose levels in venous blood using the YSI instrument. Recently, Medtrum Technologies, Inc. developed a new real-time (RT)-CGM system, Medtrum A6 TouchCare® CGM System. The present multicenter study was carried out to investigate the performance of the new RT-CGM system.

METHODS

Study Design

Interstitial glucose levels were monitored for 7 days in 63 patients with type 1 or type 2 diabetes using the Medtrum A6 TouchCare® CGM System (Fig. 1). Venous blood was collected as reference values on a randomized day of the wear period.

Fig. 1. Photograph of the Medtrum A6 TouchCare® CGM System equipment

Assessments and Analyses

- Effectiveness analysis

The plasma glucose levels measured by the YSI system were used as reference values, and each reference value was paired with the corresponding CGM system sensor reading. The primary analysis determined the agreement between the sensor values and reference values. The secondary analysis was to assess the relationship between the bias and blood glucose level.

- Safety analysis

Descriptive statistics were used to describe the safety events. Adverse events were monitored each day.

- Statistical analysis

Excel and SAS V9.2 were used to carry out statistical analysis.

RESULTS

- Among the 1,678 sensor values, 90.5% (95% *CI*: 89.1–91.9%) were within ±20%/20 mg/dL of the reference values, which met the expected accuracy.

Table 1. Agreement between paired sensor-reference values in the range of reference glucose levels

Agreement level	±10%/10 mg/dL	±15%/15 mg/dL	±20%/20 mg/dL	±30%/30 mg/dL	±40%/40 mg/dL
Total	65.7	81.5	90.5	96.9	98.9
≤70	24.0	36.0	72.0	96.0	100.0
71-180	61.2	78.1	88.2	96.3	99.0
>180	70.9	85.9	93.0	97.5	98.9

- Both Clarke error grid analysis and the type 1 diabetes consensus EGA reflect good point clinical accuracy.

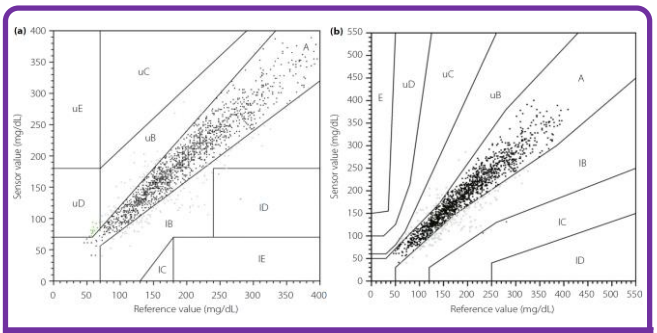

Fig. 2. (a) Clarke error grid analysis and the (b) T1DM consensus error grid analysis of the paired sensor-reference valuse

- The surveillance EGA reflect point clinical accuracy, and the continuous EGA reflects trend clinical accuracy.

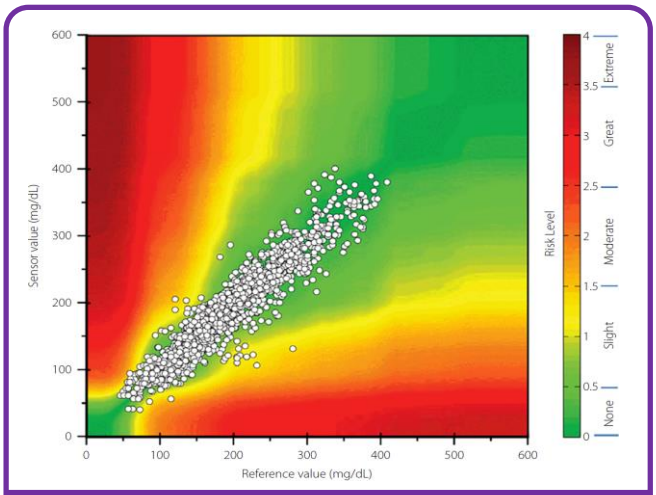

Fig. 3. Surveillance error grid analysis with risk scores

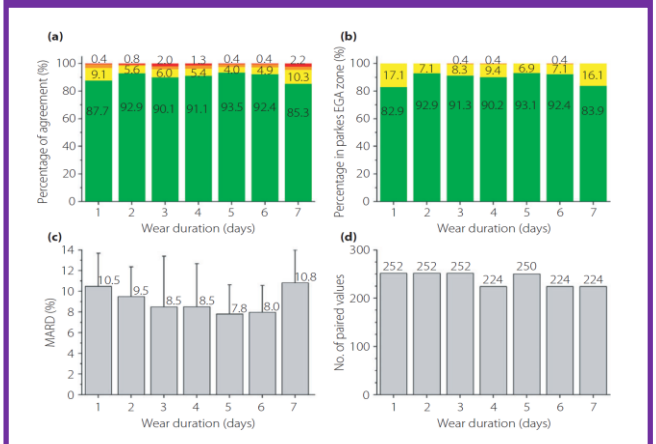

Fig. 4. (a) Percentage of agreement, (b) percentage in consensus EGA zone, (c) MARD (d) between paired sensor-reference values and the number of paired values across the wera duration

CONCLUSIONS

The Medtrum real-time continuous glucose monitoring system was numerically and clinically accurate over a large glucose range across 7 days of wear.